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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:

Applicant(s): Waranis et al.

Atty. Docket No.:

RPS 6096 US

Serial No.: 09/990,497

Examiner:

Joynes, R.

Filing Date: November 21, 2001

Art Unit:

1615

Entitled: ACETAMINOPHEN COMPOSITIONS

## CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.10(A)

Date of Deposit:

8/28/03

I hereby certify that this correspondence is being deposited with the U.S. Postal Service, as U.S. Express Mail No. EV 394968459 US in an envelope addressed to the Commissioner for Patents, ~~MAT~~ STOP PATENT APPLICATION (FEE), P.O. Box 1450, Alexandria, Virginia 22212-3513.

*Jennifer Warner*  
Jennifer Warner

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

## RESPONSE TO RESTRICTION REQUIREMENT

Sir:

This communication is responsive to the written Restriction Requirement mailed August 6, 2003. The shortened statutory period for response thereto is set for one (1) month from the date of the requirement. Accordingly, the period for response is due September 6, 2003.

The Examiner has required Applicants to elect a single disclosed species of solvent system in association with acetaminophen composition from the following:

- A. A solvent system comprising an alkali metal l-lactate salt;
- B. A solvent system comprising an alkali metal l-lactate salt and an alkali metal acetate; and
- C. A solvent system, comprising an alkali metal l-lactate salt, an alkali metal acetate, polyethyl ne glycol and polyvinyl pyrrolidone.

**Election:**

Applicants hereby elect the species of subgroup A., drawn to pharmaceutical compositions and capsular dosage forms containing acetaminophen in combination with the solvent system comprising an alkali metal l-lactate salt, as the starting point for examination. Claims 1 through 3, 9 through 11, and 17 are readable upon the elected species.

It has been noted that the Examiner regards the solvent systems as set forth above in subgroups A through C to be patentably distinct from one another. The explanation for the election of species includes the statement that no claim is currently generic to the species. However, Applicants wish to point out to the Examiner that independent claim 1 and dependent claim 2 are generic to the above groupings as defined by A, B and C, as claim 1 comprises the combination of acetaminophen and a solvent system comprising a lactate salt. No undue burden of searching would have been imposed upon the Examiner to examine all the claims thusly on the merits. Applicants reserve the right to pursue the non-elected subject matter in a separate application should the examination not address the claimed subject matter in its entirety.

**Examiner Interview:**

A telephone conversation was held on July 29, 2003 between Applicants' representatives, Andrew Rozycki and Donald Nickey, and the Examiner. During the conversation, the Examiner proposed the allowability of the specific formulation as presented in claims 7, 8 and 15. In response thereto, Applicants declined to accept the proposal, and requested a formal Office Action. Nevertheless, Applicants do wish to express their appreciation to the Examiner for his courtesy, efforts made to expedite prosecution, and the early indication of allowable subject matter in the claims.

**Conclusion:**

In light of the above, the Examiner is requested to proceed with examination on the merits. It is believed that the application is in condition for allowance, and prompt notification to that effect is earnestly solicited. The Examiner is invited to contact the undersigned to discuss the application on the merits if it is believed that such discussion would expedite the prosecution.

Dated: Aug 22, 2003

Respectfully submitted,

By: 

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